

R E M A R K S

Claims 7-24 are pending in the present application; a courtesy copy of the pending claims are provided for the Examiner's convenience only at the end of this response. The following rejections are at issue and are set forth by number in the order in which they are addressed:

- 1) Claims 9, 12, 15, 18, 21 and 24 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite (Office Action, paragraphs 5-7);
- 2) Claims 7-24 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Pariza *et al.* (US Patent No. 5,017,614, Office Action paragraph 10); and
- 3) Claims 7-24 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Llevense [sic] *et al.* (EP 0779,033 A1, Office Action, paragraph 11).

The applicants believe the following remarks traverse the Examiner's rejection of the Claims.

1. The Claims Are Not Indefinite.

Claims 9, 12, 15, 18, 21 and 24 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. The Examiner asserts that these claims recite the limitation "isomerized conjugated linoleic acid" in line 1 of claims 7, 13, 16, 19 and 22 [which are the claims from which the rejected claims depend, respectively], and that there is insufficient basis for the limitation "in the claim [sic]." The applicants do not agree with the Examiner, as "isomerized conjugated linoleic acid" is a term of art, and has been accepted in several issued patents as a description of conjugated linoleic acid produced as a result of isomerization of linoleic acid (see, for example, US Patent No. 6,015,833). Therefore, the applicants believe that these claims are not indefinite, and respectfully requests that the rejection of these claims on this basis be withdrawn.

2. The Claims are Not Obvious

Claims 7-24 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Pariza *et al.* (US Patent No. 5,017,614). The Examiner alleges that Pariza *et al.* teach compositions of

conjugated linoleic acid, specifically c9,t11 and t10,c12, and that the remaining isomers of conjugated linoleic acid contributed less than 11% of the total conjugated linoleic acid in the samples. The Examiner asserts that changes in size or range are well within the purview of the skilled artisan, citing *In re Rose*, 105 USPQ 237 (CCPA 1955), and that it would have been obvious to simply optimize the ranges disclosed in Pariza et al, "especially when the prior art ranges already encompass the instantly claimed invention."

Claims 7-24 are also rejected under 35 U.S.C. §103(a), as allegedly obvious over Llevense [sic; should be Lievense] *et al.* (EP 0779,033 A1). The Examiner alleges that Lievense *et al.* teach conjugated linoleic acid residues which more preferably contain at least 75% 9,11 octadecadienoic acid and or 10,12 octadecadienoic acid isomers. The Examiner asserts that changes in size or range are well within the purview of the skilled artisan, citing *In re Rose*, 105 USPQ 237 (CCPA 1955), and that it would have been obvious to simply optimize the ranges disclosed in Lievense *et al.* "especially when the prior art ranges already encompass the instantly claimed invention."

The applicants respectfully traverse the rejections, and in the following comments address both rejections based upon obviousness. First, the applicants are puzzled by the Examiner's assertion that the prior art ranges already encompass the instantly claimed invention. Neither reference describes or even suggests a composition, food product, or food supplement which is characterized in including less than one percent 11,13-octadecadienoic and 8,10-octadecadienoic acid isomers expressed as peak area percentage, as is claimed in the present application. In the passages cited by the Examiner, the references are completely silent as to the amount of 11,13-octadecadienoic and 8,10-octadecadienoic acid isomers; furthermore, Pariza *et al.* does not even mention 8,10-octadecadienoic acid at all, and Lievense *et al.* does not mention either 11,13-octadecadienoic acid or 8,10-octadecadienoic acid. Therefore, it is not possible for the prior art ranges to encompass the claimed invention, as there are no such ranges in the prior art.

In contrast, the applicants noted that there was a problem with most CLA products made by conventional approaches, which was their heterogeneity and substantial variation in isoform from batch to batch (specification, page 4, lines 8-10). Thus, there existed a strong need for a CLA biologically active product of defined composition. The applicants' invention both solves this problem, and satisfies this need; indeed, it is an object of the invention to

provide a safe, defined product for conjugated linoleic acid-containing compositions for consumption by both humans and animals (specification, page 4, line 26 to page 5, line 1).

The problem with conventional products was that they contained significant quantities of unknown fatty acid species and unusual isomers resulting from processing; these unusual isomers include 11,13 octadecadienoic and 8,10-octadecadienoic acid isomers (specification, page 5, lines 1-4). The applicants' solution to this problem is to use a carefully controlled reaction by which to convert a high percentage of linoleic acid to its conjugated form, resulting in the presence of less than 1 percent of the 11,13 isomers, less than 1 percent of the 8,10 isomers, less than 1 percent of the double trans species, and less than 1 percent total unidentified linoleic acid species, which is in contrast to conventional compositions (specification, page 5, lines 4-10). The 1 percent limit of these undesirable isomers thus serves as a convenient and practical quality assurance standard of purity for a commercial scale manufactured food grade product (specification, page 5, lines 10-14).

Moreover, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. (MPEP § 2143). Failure to establish **any one** of these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles an Applicant to allowance of the claims in issue. *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990). The applicants submit that the Examiner has not met even one requirement to establish a *prima facie* case of obviousness.

The Examiner has not indicated that there is ANY suggestion or motivation as to how either of the references may be modified to achieve the applicants' invention. For example, Pariza *et al.* is completely silent as to 8,10-octadecadienoic acid, and provides no information specifically about the amount of 11,13 octadecadienoic acid present; furthermore, the reference does not anywhere suggest the composition claimed in the present application, nor how to achieve such a composition, nor does the Examiner provide any suggestion or motivation from the prior art as to how the disclosures of Pariza *et al.* might be modified to achieve the applicants' invention. The Lievense *et al.* reference is completely silent about

both 11,13 octadecadienoic acid and 8,10-octadecadienoic acid, and thus provides no information about the amounts of either present in the product described. Moreover, this reference does not anywhere suggest the composition claimed in the present application, nor how to achieve it, nor does the Examiner provide any suggestion or motivation from the prior art as to how the disclosures of Lievense *et al.* might be modified to achieve the applicants' invention. Thus, the Examiner has not met the first requirement that there be some suggestion or motivation to modify either reference to achieve the claimed invention.

The Examiner has also not met the second requirement that there would be a reasonable expectation of success upon modification of either reference. Neither cited reference provides a reasonable expectation of producing a composition, food product, or food supplement which is characterized in including less than one percent 11,13-octadecadienoic and 8,10-octadecadienoic acid isomers expressed as peak area percentage, as is claimed. While the Examiner argues that it would have been obvious to optimize the ranges disclosed in either reference, neither reference provides a range to optimize, as noted above. Moreover, the Examiner appears to be arguing that it would be obvious to try to optimize the ranges, even though the Federal Circuit has held that "obvious to experiment" is not the standard for obviousness. *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988). In moving from the prior art to the claimed invention, one cannot base a determination of obviousness on what the skilled person might try or find obvious to try. The proper test requires determining what the prior art would have led a skilled person to do.

The applicants discovered a process which leads to the production of a composition, food product, or food supplement which is characterized in including less than one percent 11,13-octadecadienoic and 8,10-octadecadienoic acid isomers expressed as peak area percentage. Arriving at the desired process and products only occurred after a great deal of empirical experimentation. The applicants presented data in the specification for several aqueous and non-aqueous alkali conjugation methods. The low impurity compositions were only obtained after the careful definition of reactions conditions such as time and temperature (See specification, p. 12, lines 10-20, p. 16, line 1 to p. p18, line 8). It is the very low level of contaminating isomers resulting from these precisely controlled reactions that distinguish the presently claimed invention from the cited references. The cited references would not lead a skilled person in the art to produce the compositions of the presently claimed invention;

it would not even be obvious to try, since the references did not acknowledge that a problem existed, much less teach or even suggest how to solve it. The Examiner has apparently applied the improper “obvious to try standard” where even that standard does not apply. The Examiner has therefore not provided any reasonable expectation of success, and for this reason as well the claims should be allowed.

Finally, the Examiner has not met the third requirement that the reference must teach or suggest all of the claim limitations; the Examiner has not indicated where either reference teaches or even suggests the claimed composition, food product, or food supplement characterized in including less than one percent 11,13-octadecadienoic and 8,10-octadecadienoic acid isomers expressed as peak area percentage.

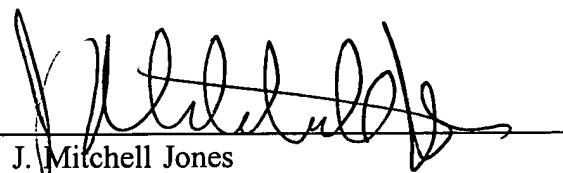
Because the Examiner has not met all three requirements, the Examiner has failed to establish a *prima facie* case of obviousness. Therefore, the applicants respectfully request that the rejections of the claims as obvious be withdrawn.

The Examiner’s contention that changes in size or range are well within the purview of the skilled artisan does not apply to the applicants’ invention. The Examiner cites *In re Rose*, 105 USPQ 237 (CCPA 1955), to support his contention. However, in this case, the appealed claims were directed to a lumber package which is composed of individually banded bundles of lumber which vary in length (*Id* at 239); although the applicant in this case argued that his claims were distinguished from that of the prior art in that the bundles of the claims were much larger and heavier so as to require handling by a lift truck, the court responded that the size of the article is not ordinarily a matter of invention (*Id* at 240). However, the applicants’ claims are directed to quite different subject matter, in which a composition, food product, or food supplement is characterized by a specified low amount of undesirable fatty acid isomers, which characteristic was not reportedly achieved in similar products previously produced by conventional means. The claimed composition is a chemical invention, which lies within an unpredictable technology; this is very different from a lumber package, which lies within a predictable technology. Even if the size of an article is not a matter of invention in a predictable technology (and this is surely fact-specific), this conclusion is not applicable to the purity of a composition in an unpredictable technology. Therefore, the Examiner’s reliance upon this case is misplaced, and the applicants respectfully request withdrawal of the rejections of the claims on this ground as well.

CONCLUSION

All grounds of rejection of the Office Action of March 22, 2001 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call Mitchell Jones collect at (608) 218-6900.

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